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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/559,311 | 04/28/2006 | Koh-Ichi Sakata | 1603/2 | 1552 |
| 25297 | 7590 | 08/31/2007 | EXAMINER | |
| JENKINS, WILSON, TAYLOR & HUNT, P. A. | | | GUSSOW, ANNE | |
| SUITE 1200, UNIVERSITY TOWER | | | ART UNIT | PAPER NUMBER |
| 3100 TOWER BOULEVARD | | | 1643 | |
| DURHAM, NC 27707 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/31/2007 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/559,311 | SAKATA ET AL. |
| | Examiner | Art Unit |
| | Anne M. Gussow | 1643 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 July 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 - 4a) Of the above claim(s) 1-5, 9 and 10 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6-8 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 6 and 7 have been amended.
Claim 11 has been added.
2. Claims 6-8 and 11 are under examination.
3. The following Office Action contains NEW GROUNDS OF REJECTION

Objections Withdrawn

4. The objections to the specification have been withdrawn in view of Applicant's amendments to the specification.

Rejections Withdrawn

5. The rejection of claims 6 and 8 under 35 U.S.C. 102(b) as being anticipated by Ogawa, et al. is withdrawn in view of Applicant's amendment to the claims.
6. The rejection of claims 6-8 under 35 U.S.C. 102(b) as being anticipated by Auckley, et al. is withdrawn in view of Applicant's amendment to the claims.

Rejections Maintained/NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 6-8, and newly added claim 11 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed July 19, 2007 has been carefully considered but is deemed not to be persuasive. The response states that chromosome abnormalities are inversely related to DNA-dependent protein kinase activity and that the accumulation of genetic mutations can lead to malignant transformations in cells, resulting in cancer (see response pages 16-17). In response to this argument, while some genetic mutations can lead to cancer, not all genetic mutations lead to cancer. Genetic mutations can be silent mutations, can lead to cell death, or can lead to cell malignancy. The correlation of just any chromosome abnormality and DNA-dependent protein kinase activity doesn't independently predict that a patient will develop cancer.

The response additionally states that the specification discloses that lymphoid cells were collected from patients suffering from breast cancer, uterine cancer, and head and neck cancer, therefore enabling the type of cancer susceptibility to be determined (page 17 of the response, and example 1 of the specification). In response to this argument, while the specification enables detection or diagnosis of breast cancer, uterine cancer, and head and neck cancer by measuring DNA-dependent protein kinase

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activity, there is no guidance provided to assist one of skill in the art to determine the susceptibility of a patient to breast cancer, uterine cancer or head and neck cancer before the patient has the cancer. As set forth in the previous office action, susceptibility is defined as the likelihood of an individual to develop ill effects from an external agent. Applicant's specification has demonstrated that a patient who has breast, uterine, or head and neck cancer also has abnormal DNA-dependent protein kinase activity however; there is no evidence to support the idea that abnormal DNA-dependent protein kinase activity leads to the formation of cancer. Also, there is no evidence provided to assist one of skill in the art in determining how far in advance of the cancer diagnosis the abnormal kinase activity is present. Does the abnormal kinase activity mean that a patient will develop cancer in a few days, months, or years? Thus, there is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to determine susceptibility to breast cancer, uterine cancer, or head and neck cancer by measuring DNA-dependent protein kinase activity.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

August 29, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER